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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,646	07/23/2003	Tiecheng A. Qiao	85505KNM	9727

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EXAMINER	
GROSS, CHRISTOPHER M	
ART UNIT	PAPER NUMBER
1639	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/625,646	QIAO ET AL.	
	Examiner	Art Unit	
	Christopher M. Gross	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *06 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *17-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/6/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Responsive to communications entered 10/6/2006. Claims 1-28 are pending. Claims 17-27 are withdrawn. Claims 1-16, 28 are under consideration.

Priority

This application has a filing date of 7/23/2003. Applicant makes no claim for the benefit of any prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c).

Information Disclosure Statement

The information disclosure statement submitted on 10/6/2006 has been considered by the examiner.

Withdrawn Rejections

The rejection of claim 1 and dependent claims 2-15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn in view of Applicant's arguments.

The rejection of claim 16 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn in view of Applicant's amendment.

The provisional rejection of claims 1-16 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of copending Application No. 10682271 in view of any of Dorogushin et al (Soviet Union

Patent SU308662 – IDS entry 1/21/2005 transferred to PTO-892), Himmelmann et al (US Patent 3480431) or Bauer et al (US Patent 5639589 – IDS entry 1/21/2005) has been withdrawn in view of the terminal disclaimer filed 10/20/2006.

The rejection of claims 1,2,6,9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of **Dorogushin et al** (Soviet Union Patent SU308662 – IDS entry 1/21/2005 transferred to PTO-892), **Himmelmann et al** (US Patent 3480431), each taken separately, in view of **Fiebag** (US Patent 6143479) has been withdrawn in view of Applicant's arguments.

Maintained Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,2,6,9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Dorogushin et al (Soviet Union Patent SU308662 – IDS entry 1/21/2005 transferred to PTO-892). This rejection maintains the reasons set forth in the previous Office action.

Response to Arguments

Applicant argues that not all elements are taught by Dorogushin et al.

Applicant's arguments have been considered but they are not persuasive for the following reasons.

Applicant argues, see p 8 (10/6/2006), that Dorogushin et al fails to explictly disclose a gelatin layer which would be useful as a protein microarray.

In response to applicant's arguments, the recitation 'useful as a protein microarray' has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Applicant argues, see p 8 (10/6/2006), the gelatin layer according to Dorogushin does not contain functional groups capable of specific binding of biological probes. However, as mentioned in the last office action, and evidenced by Schor et al (1996 J. Cell Sci. 109:2581-2590), fibronectin is a protein which binds denatured collagen (a.k.a. gelatin). In particular, on page 2583, right column, first paragraph last line Schor use gelatin-agarose chromatography to affinity purify fibronectin expressed in insect cells. Thus, according to Schor et al gelatin acts as a specific binder for fibronectin and therein gelatin inherently bears functional groups capable of specific binding biological probes, such as fibronectin.

Claims 1,2,6,9-10,12 are rejected under 35 U.S.C. 102(b) as being anticipated by Himmelmann et al (US Patent 3480431). This rejection maintains the reasons set forth in the previous Office action.

Applicant argues that not all elements are taught by Himmelmann et al.

Applicant's arguments have been considered but they are not persuasive for the following reasons.

Applicant argues, see p 10 (10/6/2006), that Himmelmann et al fails to explictly disclose a gelatin layer which would be useful as a protein microarray.

In response to applicant's arguments, the recitation 'useful as a protein microarray' has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Applicant argues, see p10 (10/6/2006), the gelatin layer according to Himmelman et al does not contain functional groups capable of specific binding of biological probes. However, as mentioned in the last office action, and evidenced by Schor et al (1996 J. Cell Sci. 109:2581-2590), fibronectin is a protein which binds denatured collagen (a.k.a. gelatin). In particular, on page 2583, right column, first paragraph last line Schor use gelatin-agarose chromatography to affinity purify fibronectin expressed in insect cells. Thus, according to Schor et al gelatin acts as a specific binder for fibronectin and therein gelatin inherently bears functional groups capable of specific binding biological probes, such as fibronectin.

Claims 1,2,6,9 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Bauer et al (US Patent 5639589 – IDS entry 1/21/2005). This rejection maintains the reasons set forth in the previous Office action.

Applicant argues that not all elements are taught by Bauer et al.

Applicant's arguments have been considered but they are not persuasive for the following reasons.

Applicant argues, see p 11 (10/6/2006), that Bauer et al fails to explictly disclose a gelatin layer which would be useful as a protein microarray.

In response to applicant's arguments, the recitation 'useful as a protein microarray' has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Applicant argues, see p 11 (10/6/2006) the gelatin layer according to Bauer et al does not contain functional groups capable of specific binding of biological probes. However, as mentioned in the last office action, and evidenced by Schor et al (1996 J. Cell Sci. 109:2581-2590), fibronectin is a protein which binds denatured collagen (a.k.a. gelatin). In particular, on page 2583, right column, first paragraph last line Schor use gelatin-agarose chromatography to affinity purify fibronectin expressed in insect cells.

Thus, according to Schor et al gelatin acts as a specific binder for fibronectin and therein gelatin inherently bears functional groups capable of specific binding biological probes, such as fibronectin.

Maintained Claim Rejections 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,2,6,9-12,15 and 7,8 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of **Dorogushin et al** (Soviet Union Patent SU308662 – IDS entry 1/21/2005 transferred to PTO-892), **Himmelmann et al** (US Patent 3480431) or **Bauer et al** (US Patent 5639589 – IDS entry 1/21/2005), each taken separately, each in view of **Roberts et al** (US Patent 5380642). This rejection maintains the reasons set forth in the previous Office action.

Applicant argues (i) not all elements are taught (ii) the above references lack an expectation of success and (iii) the present invention represents unexpected results.

Applicant's arguments have been considered but they are not persuasive for the following reasons.

(i) In regard to not all elements being taught, see Applicant's Arguments, see p 15 (10/6/2006): As discussed above, each of the gelatin films of Dorogushin et al, Himmelmann et al Bauer et al inherently comprise functional groups capable of specific binding to fibronectin.

(ii-iii) In so far as an expectation of success is concerned, Applicant's argues p 15 (10/6/2006) that the instant specification provides evidence on pg 18, line 16 and pg

19 line 2 that gelatin is a known non-specific binder as demonstrated in US Patent 6,797,393 however, applicant's attention is respectfully invited to pg 3, line 2 of the instant specification, which states a gelatin modified surface effectively eliminates non-specific protein binding, a teaching stemming from application 10/020747 (now US Patent 6,797,393). Furthermore, if gelatin can act as an effective blocking agent, as taught in US Patent 6,797,393, the present invention does not represent a surprising result because one of ordinary skill in the art would not be dissuaded from using gelatin as part of an immobilization surface, for fear of adventitious protein binding, and in fact, as evidenced by Schor et al agarose-gelatin represents an effective means of purifying fibronectin recognized in the prior art, therein, absent evidence to the contrary, the gelatin of Dorogushin et al, Himmelmann et al Bauer would similarly specifically immobilize fibronection.

Claims 1,2,6,9-12,15 and 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of **Dorogushin et al** (Soviet Union Patent SU308662 – IDS entry 1/21/2005 transferred to PTO-892), **Himmelmann et al** (US Patent 3480431) or **Bauer et al** (US Patent 5639589 – IDS entry 1/21/2005), each taken separately, each in view of **Arenkov et al** (2000 Analytical Biochemistry 278:123-131– IDS entry 11/10/2003 transferred to PTO-892). This rejection maintains the reasons set forth in the previous Office action.

Applicant argues (i) not all elements are taught (ii) the above references lack an expectation of success and (iii) the present invention represents unexpected results.

Applicant's arguments have been considered but they are not persuasive for the following reasons.

(i) In regard to not all elements being taught, see Applicant's Arguments p 18 (10/6/2006): As discussed above, each of the gelatin films of Dorogushin et al, Himmelmann et al Bauer et al inherently comprise functional groups capable of specific binding to fibronectin.

(ii-iii) In so far as an expectation of success is concerned, Applicant's argues p 19 (10/6/2006) that the instant specification provides evidence on pg 18, line 16 and pg 19 line 2 that gelatin is a known non-specific binder as demonstrated in US Patent 6,797,393 however, applicant's attention is respectfully invited to pg 3, line 2 of the instant specification, which states the gelatin modified surface effectively eliminates non-specific protein binding, a teaching stemming from application 10/020747 (now US Patent 6,797,393). Furthermore, if gelatin can act as an effective blocking agent, as taught in US Patent 6,797,393, the present invention does not represent a surprising result because one of ordinary skill in the art would not be dissuaded from using gelatin as part of an immobilization surface, and in fact, as evidenced by Schor et al agarose-gelatin represents an effective means of purifying fibronectin recognized in the prior art, therein, absent evidence to the contrary, the gelatin of Dorogushin et al, Himmelmann et al Bauer would similarly specifically immobilize fibronection.

Claims 1,2,6,9-12,15 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of **Dorogushin et al** (Soviet Union Patent SU308662 – IDS entry

1/21/2005 transferred to PTO-892), **Himmelmann et al** (US Patent 3480431) or **Bauer et al** (US Patent 5639589 – IDS entry 1/21/2005), each taken separately, each in view of **Christopher** (US Patent 2309340). This rejection maintains the reasons set forth in the previous Office action.

Applicant argues (i) not all elements are taught (ii) the above references lack an expectation of success and (iii) the present invention represents unexpected results.

Applicant's arguments have been considered but they are not persuasive for the following reasons.

(i) In regard to not all elements being taught, see Applicant's Arguments p 21 (10/6/2006): As discussed above, each of the gelatin films of Dorogushin et al, Himmelmann et al Bauer et al inherently comprise functional groups capable of specific binding to fibronectin.

(ii-iii) In so far as an expectation of success is concerned, Applicant's argues p 21-22 (10/6/2006) that the instant specification provides evidence on pg 18, line 16 and pg 19 line 2 that gelatin is a known non-specific binder as demonstrated in US Patent 6,797,393 however, applicant's attention is respectfully invited to pg 3, line 2 of the instant specification, which states the gelatin modified surface effectively eliminates non-specific protein binding, a teaching stemming from application 10/020747 (now US Patent 6,797,393). Furthermore, if gelatin can act as an effective blocking agent, as taught in US Patent 6,797,393, the present invention does not represent a surprising result because one of ordinary skill in the art would not be dissuaded from using gelatin as part of an immobilization surface for fear of adventitious protein binding, and in fact,

as evidenced by Schor et al agarose-gelatin represents an effective means of purifying fibronectin recognized in the prior art, therein, absent evidence to the contrary, the gelatin of Dorogushin et al, Himmelmann et al Bauer would similarly specifically immobilize fibronection.

Claims 1,2,6,9-12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of **Dorogushin et al** (Soviet Union Patent SU308662 – IDS entry 1/21/2005 transferred to PTO-892), **Himmelmann et al** (US Patent 3480431) or **Bauer et al** (US Patent 5639589 – IDS entry 1/21/2005), each taken separately, in view of **Bonderman** (US Patent 5348852). This rejection maintains the reasons set forth in the previous Office action.

Applicant argues (i) not all elements are taught (ii) the above references lack an expectation of success and (iii) the present invention represents unexpected results.

Applicant's arguments have been considered but they are not persuasive for the following reasons.

(i) In regard to not all elements being taught, see Applicant's Arguments p 24 (10/6/2006): As discussed above, each of the gelatin films of Dorogushin et al, Himmelmann et al Bauer et al inherently comprise functional groups capable of specific binding to fibronectin.

Applicant argues, p 25 (10/16/2006) that fish gelatin of Bonderman would not produce a layer of gelatin and thus rendering the reference inoperable for its intended purpose. Specifically, applicant argues p25 (10/6/2006) the gelatin of Bonderman et al

would not produce a layer on the support because of its labile nature and resistance to gelation. However, applicant's attention respectfully invited to column 4, line 5 of Bonderman et al which states that "the composition is gelatin from cold water fish skin, which has demonstrated a gelling temperature substantially lower than that of typical land animals such as cows or pigs" Thus, gellation still occurs, and absent evidence to the contrary, the fish gelatin according to Bonderman et al is fully capable of forming a layer, albeit at a lower temperature.

(ii-iii) In so far as an expectation of success is concerned, Applicant's argues p 25 (10/6/2006) that the instant specification provides evidence on pg 18, line 16 and pg 19 line 2 that gelatin is a known non-specific binder as demonstrated in US Patent 6,797,393 however, applicant's attention is respectfully invited to pg 3, line 2 of the instant specification, which states the gelatin modified surface effectively eliminates non-specific protein binding, a teaching stemming from application 10/020747 (now US Patent 6,797,393). Furthermore, if gelatin can act as an effective blocking agent, as taught in US Patent 6,797,393, the present invention does not represent a surprising result because one of ordinary skill in the art would not be dissuaded from using gelatin as part of an immobilization surface, for fear of adventitious protein binding, and in fact, as evidenced by Schor et al agarose-gelatin represents an effective means of purifying fibronectin recognized in the prior art, therein, absent evidence to the contrary, the gelatin of Dorogushin et al, Himmelmann et al Bauer would similarly specifically immobilize fibronection.

New Claim Rejections - 35 USC § 103

Claims 16 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of **Dorogushin et al** (Soviet Union Patent SU308662 – IDS entry 1/21/2005 transferred to PTO-892), **Himmelmann et al** (US Patent 3480431) or **Bauer et al** (US Patent 5639589 – IDS entry 1/21/2005), each taken separately, **each in view of Arenkov et al** (2000 Analytical Biochemistry 278:123-131– IDS entry 11/10/2003 transferred to PTO-892) as applied to claims 1,2,6,9-12,15 and 3-5 above, and further in view of **Cone et al** (US Patent 2235202).

This rejection is necessitated by Applicant's amendment to the claims.

Any of Dorogushin et al, **Himmelmann et al**, and **Bauer et al in view of Arkenov et al** are relied on as above and per the last Office Action.

Any of Dorogushin et al, **Himmelmann et al**, and **Bauer et al in view of Arkenov et al** do not teach a silicate salt, however. **Any of Dorogushin et al**, **Himmelmann et al**, and **Bauer et al in view of Arkenov et al** do not teach a gelatin layers 10 to 50 grams per square meter, as set forth in claim 16.

Cone et al teach, throughout the document and especially p1, paragraphs 1-2 glue made from collagen and various tannins.

Cone et al teach in claim 10, the use of an alkali metal silicate, which is taken as the silicate salt of claims 12 and 28 (c).

It would have been *prima facie* obvious for one of ordinary skill in the art, at the time the claimed invention was made to use the Corning Micro Slide and employing bisacrylamide as a crosslinker of Arenkov et al with the gelatin based films capable

performing as protein microarrays of Dorogushin, Himmelmann or Bauer and incorporate the silicate salt per Cone et al.

One of ordinary skill in the art would have been motivated to use the Corning Micro Slide and employing bisacrylamide as a crosslinker of Arenkov et al with the gelatin based films capable performing as protein microarrays of Dorogushin, Himmelmann or Bauer and incorporate the silicate salt per Cone et al. because it would impove the adhesive qualities of the gelatin, as noted by Cone in column 1, line 20.

In so far as the gelatin layers being 10 to 50 grams per square meter, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) See MPEP 2144.05 A.

One of ordinary skill in the art could have used the Corning Micro Slide employing bisacrylamide as a crosslinker of Arenkov et al with the gelatin based films capable performing as protein microarrays of Dorogushin, Himmelmann or Bauer and incorporate the silicate salt per Cone et al. with a reasonable expectation of success since the glue of Cone lies well within the scope of the gelatin technology of each of Dorogushin, Himmelmann or Bauer.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Gross whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz can be reached on 571 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher M Gross
Examiner
Art Unit 1639

cg

JON EPPERSON
PRIMARY EXAMINER